

Notice of Allowability

Application No.

10/686,326

Examiner

Julian W. Woo

Applicant(s)

WELLER ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment of 1/13/06.
2. ☒ The allowed claim(s) is/are 1, 2, 3-5, 8-10, 13, 15, 16, 19, 22, 23, 26, 28, 29, 33, 34, 37, 40, 41, 43-66, 68, 69, 71, 72, 76-101.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>12/18/06</u> <u>12/15/06</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

2. The application has been amended as follows:

In claim 1, line 7, delete "inlcudes" and in its place, insert --includes--.

3. The following is an examiner's statement of reasons for allowance: With respect to claim 1: None of the prior art of record, alone or in combination, discloses a tissue acquisition and fixation system including, inter alia, a tissue acquisition device with an elongate main body defining a main lumen therethrough, where the distal end of the acquisition device is adapted to acquire tissue, and a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen, where the device comprises a flexible shaft. With respect to claim 79, the tissue acquisition device further includes a first acquisition member that is articulatable via an actuation rod disposed along a length of the main body; and with respect to claims 80 and 81, first and second acquisition members are individually articulatable. With respect to claim 82: the tissue acquisition device further includes first and second acquisition members, where each acquisition member includes at least one opening positionable in offset apposition to one another. With respect to claim 83: the tissue acquisition device includes first and second acquisition members, where each acquisition member

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comprises a tensioning member; and with respect to claim 84, each acquisition member comprises a hinge member. With respect to claim 85, the tissue acquisition device includes first and second acquisition members, where the acquisition members are adapted to rotate into an offset configuration. With respect to claims 86 and 88: the tissue acquisition device further includes a distal end that defines a guidewire lumen and is positionable with a guidewire. With respect to claim 87, the tissue acquisition device further includes a tapered atraumatic distal tip comprising a polymeric material. With respect to claims 89 -92: the tissue acquisition device further includes a main body that is actively or passively curved, uni-directionally curved, or curved in a plurality of directions. With respect to claim 93, the tissue acquisition device further includes a handle, where the handle includes a gasket. With respect to claim 94, the main body of the tissue acquisition device further comprises a plurality of adjacent links. With respect to claim 95, the tissue acquisition device further includes two opposing members that are adapted to flex via a plurality of pivots. With respect to claim 96, the tissue fixation device further includes a handle that is adapted to deploy a plurality of staples from the cartridge assembly; and with respect to claim 97, the cartridge assembly further comprises a stapler housing and an anvil. With respect to claims 50 and 101: The prior art also does not teach or fairly suggest a method of acquiring and affixing tissue with the system as claimed, where, inter alia, the elongate main body has a first acquisition member that is articulated to acquire tissue, which is brought into contact with a tensioning member, and where the tissue is folded and affixed via cartridge assembly which is adapted to maintain a predetermined orientation relative to the main lumen of

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the elongated main body. With respect to claim 66: The prior art does not teach or fairly suggest a method of manipulating tissue from within a hollow body organ with the system as claimed, where the method includes, inter alia, an acquisition member that is advanced transorally. With respect to claim 98, the method as claimed further includes positioning a distal end of the elongate main body within a hollow body organ, where at least one portion of the main body is articulated by inserting a curved stylet within the main body. With respect to claims 99 and 100, the method as claimed further includes curving at least one portion of the main body.

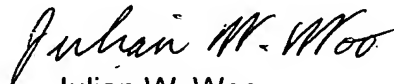
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is 571-272-4707. The examiner can normally be reached on M-F, 6:30-4:00, Alt. Fri. OFF; 6:30-3:00 Fri. IN.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner
Art Unit 3731

March 21, 2006